Claims

1. A pharmaceutical excipient comprising a solid, reticulated matrix, wherein the matrix comprises an aggregation of inorganic particles in association with an organic polymeric material, defines a plurality of pores with a mean width in the range of about 0.01-500μm, and has a specific surface area of at least about 1 m^2/g.

2. An excipient as claimed in claim 1, wherein the pores have a mean width in the range of about 0.1-500μm and the matrix has a specific surface area of no more than about 100m^2/g.

3. An excipient as claimed in claim 1 or 2, wherein the mean width of the pores is in a range of about 0.5-300, 1-200, 3-100, 5-80, 15-70, 20-60 or 0.1-10μm.

4. An excipient as claimed in any of the preceding claims, wherein the matrix has a specific surface area of at least about 2, 3, 4, 5, 10 or 20 m^2/g, and/or up to about 100, 50 or 40m^2/g.

5. An excipient as claimed in any of the preceding claims, wherein the inorganic particles are crystalline.

6. An excipient as claimed in any of the preceding claims, wherein the aggregation of inorganic particles comprises a plurality of discrete crystals.

7. An excipient as claimed in any of the preceding claims, wherein the mean width of the inorganic particles is about 0.1-50μm.

8. An excipient as claimed in any of the preceding claims, wherein the pores comprise primary and secondary pores, the primary pores have a mean width of about 2-500μm and are defined between structural elements formed from the matrix, the secondary pores have a mean width of 0.01–10μm and are defined

within said structural elements, and the mean width of the secondary pores is less than the mean width of the primary pores.

9. A pharmaceutical excipient comprising a solid, reticulated matrix, wherein the matrix comprises an inorganic material in association with an organic polymeric material, a plurality of primary pores with a mean width of about 2-500μm are defined between structural elements formed from the matrix, a plurality of secondary pores with a mean width of about 0.01–10μm are defined within said structural elements, and the mean width of the secondary pores is less than the mean width of the primary pores.

10. An excipient as claimed in claim 9, wherein matrix has a specific surface area of at least 0.1, 0.5, 1, 3, 4, 5, 10 m^2/g, and or up to about 100, 50 or 40m^2/g.

11. An excipient as claimed in any of claims 8-10, wherein the mean width of the primary pores is at least about 5, 10, 20 or 40μm, and/or no more than about 300, 200, 100 or 50μm.

12. An excipient as claimed in any of claims 8-11, wherein the mean width of the secondary pores is at least about 0.01, 0.05, or 0,1μm, and/or no more than about 5, 3, 2, 1.5 or 1μm.

13. An excipient as claimed in any of claims 8-12, wherein at least about 50, 55, 70, 80, 90, or 95% of the primary pores have a width that is greater than the mean width of the secondary pores, and/or at least about 50, 55, 70, 80, 90, or 95% of the secondary pores have a width that is less than the mean width of the primary pores.

14. An excipient as claimed in any of claims 8-13, wherein the structural elements form primary walls that define the primary pores, and comprise a network of secondary walls that define the secondary pores.

15. An excipient as claimed in claim 16, wherein the primary walls have a mean width of about 10-500, 10-200, 20-100 or 10-50μm, and/or the secondary walls have a mean width of about 0.01-5 or 0.5-2μm.

16. An excipient as claimed in any of claims 1-13, wherein the matrix is in the form of a plurality of agglomerations of organic polymeric material and inorganic particles or material, in which the secondary pores are formed.

17. An excipient as claimed in claim 19, wherein the primary pores are located between adjacent agglomerations.

18. An excipient as claimed in any of claims 8-17, wherein the inorganic material is particulate.

19. An excipient as claimed in claim 18, wherein the inorganic material is crystalline and, optionally, comprises a plurality of discrete crystals.

20. An excipient as claimed in any of claims 8-19, wherein the mean width of the organic particles is within the range of about 0.1-50μm.

21. An excipient as claimed in any of the preceding claims, wherein the organic polymeric material binds the inorganic particles or material into the matrix.

22. An excipient as claimed in any of the preceding claims, wherein the organic polymeric material forms a template for the inorganic particles or material.

23. An excipient as claimed in any of the preceding claims, wherein the matrix consists essentially or solely of an aggregation of inorganic particles in association with an organic polymeric material.

24. An excipient as claimed in any of the preceding claims consisting essentially or solely of the matrix.

25. An excipient as claimed in any of the preceding claims, comprising from about 5 to about 95% by weight of said polymeric material or template.

26. An excipient as claimed in any of the preceding claims, wherein the organic polymeric material is at least readily soluble in water at a temperature of between 20 and 50°C within a period of 24 hours.

27. An excipient as claimed in any of the preceding claims, wherein the polymeric material comprises a polysaccharide and/or a protein.

28. An excipient as claimed in any of the preceding claims, wherein the polymeric material comprises xanthan gum, dextran, acacia gum and/or egg albumen.

29. A pharmaceutical excipient comprising a porous network of fused inorganic elements, said network defining a plurality of pores with a mean width within the range of about 0.01-100μm.

30. An excipient as claimed in claim 29, wherein the inorganic elements have a mean width of no more than about 10, 5 or 2μm.

31. An excipient as claimed in claim 29 or 30, wherein the inorganic elements are at least partially crystalline.

32. An excipient as claimed in any of claims 29-31, wherein the pores comprise primary and secondary pores, the primary pores have a mean width of about 2-500μm and are defined between structural elements formed from the matrix, the secondary pores have a mean width of 0.01–10μm and are defined within said structural elements, and the mean width of the secondary pores is less than the mean width of the primary pores.

33. An excipient as claimed in claim 32, wherein the mean width of the primary pores is at least about 5, 10, 20 or 40μm, and/or no more than about 300, 200, 100 or 50μm.

34. An excipient as claimed in claim 32 or 33, wherein the mean width of the secondary pores is at least about 0.01, 0.05, or 0.1μm and/or no more than about 5, 3, 2, 1.5 or 1μm.

35. An excipient as claimed in any of claims 32-34, wherein at least about 50, 55, 70, 80, 90, or 95% of the primary pores have a width that is greater than the mean width of the secondary pores and/or at least about 50, 55, 70, 80, 90, or 95% of the secondary pores have a width that is less than the mean width of the primary pores.

36. An excipient as claimed in any of claims 32-35, wherein the structural elements form primary walls that define the primary pores, and comprise a network of secondary walls that define the secondary pores.

37. An excipient as claimed in claim 36, wherein the primary walls have a mean width of about 10-500, 10-200, 20-100 or 10-50μm, and/or the secondary walls have a mean width of about 0.01-5 or 0.5-2μm.

38. An excipient as claimed in any of claims 29-31 comprising a plurality of pores with a mean width of 0.01-50μm.

39. An excipient as claimed in any of claims 29-38 consisting essentially or solely of said fused inorganic elements.

40. An excipient as claimed in any of the preceding claims, wherein the inorganic material comprises or the inorganic particles comprise silica and/or a pharmaceutical acceptable alkaline earth metal salt.

41. An excipient as claimed in any of the preceding claims, wherein the inorganic material comprises or the inorganic particles comprise calcium phosphate and/or calcium carbonate.

42. An excipient as claimed in any of the preceding claims in particulate form.

43. An excipient as claimed in any of the preceding claims with a bulk density in the range of 0.25-1.5 g/cm^3 and/or a tap density in the range of 0.5-2 g/cm^3.

44. A method of preparing a solid, reticulated matrix including the steps of, forming a reticulated template comprising an organic polymeric material, forming a construct comprising an aggregation of inorganic particles in association with said template, and solidifying said construct to form a solid, reticulated matrix comprising the inorganic particles in association with the inorganic polymeric material, where said matrix defines a plurality of pores with a mean width of 0.01-500μm and/or has a specific density of at least 1m^2/g.

45. A method as claimed in claim 44, wherein the reticulated template, aggregation of inorganic particles and the construct are formed substantially simultaneously.

46. A method as claimed in claim 44 or 45, wherein the reticulated template is formed by dispersing a second phase in a liquid phase that comprises the organic polymeric material.

47. A method as claimed in claim 46, wherein said second phase comprises or consists essentially of solid particles and/or gas bubbles.

48. A method as claimed in claim 46 or 47, wherein the liquid phase comprises a solution of the organic polymeric material.

49. A method as claimed in claim 47 or 48, wherein the solid particles are soluble in a solvent in which the organic polymeric material, once set or solidified, is substantially insoluble.

50. A method as claimed in claim 49, wherein the inorganic particles are substantially insoluble in said solvent.

51. A method as claimed in any of claims 44-50, wherein the reticulated template is spontaneously formed from a solution of organic polymeric material, or by the action of a cross-linking agent on a dissolved organic polymeric material.

52. A method as claimed in any of claims 44-51, wherein the reticulated template is formed from an aqueous solution of the polymeric material.

53. A method as claimed in any of claims 44-52, wherein, a proportion of the inorganic particles are formed by precipitation from a solution comprising the organic polymeric material.

54. A method as claimed in claim 53, wherein the inorganic particles comprise an inorganic salt and said solution further comprises dissolved anions and/or cations of said salt.

55. A method as claimed in claim 54, wherein, before precipitation is initiated, said solution includes dissolved anions but substantially no dissolved cations, or dissolved cations and substantially no dissolved anions of the salt.

56. A method as claimed in claim 55, wherein precipitation is caused by the addition of a solution comprising the counter ions required to form the salt.

57. A method as claimed in claim 53, wherein formation of the inorganic particles by precipitation can take place during or after the formation of the reticulated template.

58. A method as claimed in any of claims 44-57, wherein at least a proportion of and, optionally, substantially all of the inorganic particles are pre-formed and dispersed in a liquid phase which comprises the organic polymeric material.

59. A method as claimed in any of claims 44-57, wherein substantially all of the inorganic particles are formed by precipitation from a solution comprising the organic polymeric material.

60. A method as claimed in any of claims 54-59, wherein the inorganic particles are crystalline.

61. A method as claimed in any of claims 44-60, wherein the mean width of the particles or crystals of inorganic material is in the range of about 0.1-50μm.

62. A method as claimed in any of claims 44-61, wherein the aggregation of inorganic particles forms a part of the reticulated template.

63. A method as claimed in any of claims 44-62, wherein the construct of reticulated template and aggregation of inorganic particles is solidified by air-drying, spontaneous cross-linking, the action of a cross-linking agent, the effect of a temperature change, the act of forming the inorganic particles by precipitation and/or the influence of electro-magnetic radiation.

64. A method as claimed in claim 44 or 45, wherein the reticulated template is formed by entraining gas bubbles in a liquid phase comprising the organic polymeric material, and at least a proportion of the inorganic particles are caused to precipitate during said entrainment process.

65. A method as claimed in claim 44 or 45, wherein the reticulated structure is formed by distributing solid particles in a liquid phase comprising the organic polymeric material and the solid particles are removed after the construct has been solidified by dissolution in an appropriate solvent.

66. A method as claimed in claim 64 or 65, wherein the liquid phase comprises a solution of the organic polymeric material.

67. A method as claimed in any of claims 44-66, wherein the organic polymeric material includes or is a polysaccharide and/or a protein.

68. A method as claimed in any of claims 44-67, wherein the inorganic particles comprise an alkaline earth metal carbonate and/or phosphate.

69. A method as claimed in claim 68, comprising the steps of forming an aqueous solution of an organic polymeric material and a soluble phosphate or carbonate salt and causing the alkaline earth metal carbonate or phosphate inorganic particles to precipitate from said solution by the addition of an aqueous solution of a soluble salt of the alkaline earth metal.

70. A method as claimed in claim 69, wherein the soluble salt of the alkaline earth metal is a chloride.

71. A method as claimed in any of claims 44-70, wherein the inorganic particles comprise calcium carbonate and/or calcium phosphate.

72. A method as claimed in any of claims 53-79, wherein the organic polymeric material is at least readily soluble in water at a temperature between 20 and 50°C within a period of 24 hours.

73. A method as claimed in any of claims 44-72, wherein the polymeric material comprises a polysaccharide and/or a protein.

74. A method as claimed in any of claims 44-73, wherein the polymeric material comprises xanthan gum, dextran, acacia gum and/or egg albumen.

75. A method as claimed in claim 65, wherein the solid particles employed to form the reticulated template are formed from latex.

76. A method for preparing a pharmaceutical excipient comprising the step of preparing a solid, reticulated matrix by a method as claimed in any of claims 44-75.

77. A method for preparing a pharmaceutical excipient as claimed in any of claims 1-43, comprising the step of preparing the solid, reticulated matrix by a method as claimed in any of claims 44-75.

78. A method for preparing a pharmaceutical excipient as claimed in any of claims 29-43, comprising heating a solid, reticulated matrix of organic polymeric material and inorganic particles to a sufficiently high temperature to both eliminate the organic polymeric material and cause the inorganic particles to fuse together into a second solid, reticulated matrix defining a plurality of pores with a mean width of up to 100μm.

79. A method as claimed in claim 78, wherein the organic polymeric material is eliminated and the organic particles caused to fuse by heating the solid, reticulated matrix to a temperature of about 800 to 1600°C.

80. A method as claimed in claim 78 or 79, wherein the solid, reticulated matrix of organic polymeric material and inorganic particles is prepared, or preparable, by a method as claimed in any of claims 44-75 and/or is a matrix as defined in any of claims 1-28.

81. A method as claimed in any of claims 78-80, wherein the solid, reticulated matrix is heated to a temperature of up to about 1100°C or about 1050°C.

82. A method as claimed in any of claims 78-80, wherein the solid, reticulated matrix is heated to a temperature in excess of 1100°C, optionally, to a temperature within the range of about 1200 or 1250-1500°C.

83. A pharmaceutical excipient comprising a solid, reticulated matrix prepared or preparable by a method as claimed in any of claims 44-82.

84. A pharmaceutical excipient as claimed in any of claims 1-28 prepared or preparable by a method as claimed in any one of claims 44-77.

85. A pharmaceutical excipient as claimed in any of claims 29-43 prepared or preparable by a method as claimed in any one of claims 78-82.

86. A pharmaceutical product comprising a pharmaceutical excipient as claimed in any of claims 1-43 and 82-84, and a pharmaceutically active agent.

87. A pharmaceutical product as claimed in claim 87, wherein the pharmaceutically active agent is particulate and solid.

88. A pharmaceutical product as claimed in claim 86 or 87, wherein the pharmaceutically active agent is intimately associated with the excipient.

89. A pharmaceutical product as claimed in any of claims 86-88, wherein the pharmaceutically active agent is located within the pores of the solid, reticulated matrix and/or coated onto the matrix or excipient.

90. A pharmaceutical product as claimed in any of claims 86-89, wherein the pharmaceutically active agent lies within Class 2 in the FDA adopted Biopharmaceutical Classification System (BCS).

91. A pharmaceutical product as claimed in any of claims 86-90, wherein the pharmaceutically active agent has an aqueous solubility of up to about 1 in 30 or 1 in 100 weight/volume, when measured at a temperature in the range of 15 to 25°C.

92. A pharmaceutical product as claimed in any of claims 86-91, wherein the pharmaceutically active agent is crystalline.

93. A pharmaceutical product as claimed in any of claims 86-92, wherein the pharmaceutically active agent is particulate, optionally crystalline, and the particles

and/or crystals of pharmaceutically active agent have a mean width of about 10nm - 10μm, 10nm-5μm or less than about 1μm.

94. A pharmaceutical product as claimed in any of claims 86-93, comprising from about 1 to about 50% W/W pharmaceutically active agent.

95. A pharmaceutical product as claimed in any of claims 86-94, including an additional pharmaceutically acceptable excipient and/or diluent.

96. A pharmaceutical product as claimed in any of claims 86-95, in the form of an oral solid dosage form.

97. A pharmaceutical product as claimed in claim 96, in the form of a powder, capsule or tablet.

98. A method of treatment or diagnosis, comprising administering a pharmaceutical product as claimed in any of claims 86-97 to a human or animal patient.

99. An excipient as claimed in any of claims 1-43 and 83-85 or a product as claimed in any of claims 86-97 for use in medicine.

100. The use an excipient as claimed in any of claims 1-43 and 83-85 or a product as claimed in any of claims 86-97 for the manufacture of a medicament for use in a therapeutic or diagnostic method practised on the human or animal body.

101. A pharmaceutical excipient, comprising a pharmaceutically acceptable alkaline earth metal salt in crystalline form coated onto the surface of a polymeric template comprising a pharmaceutically acceptable polymeric substance, said excipient having a specific surface area greater than $10m^2/g$.

102. A pharmaceutical excipient, comprising a porous matrix consisting essentially of a pharmaceutically acceptable alkaline earth metal salt in crystalline form in

intimate association with a polymeric template, said excipient having a specific surface area greater than $10m^2/g$.

103. The pharmaceutical excipient of any of claims 101-102, wherein the structure of the excipient is a construct comprising strands defining primary walls, said primary walls comprised of (i) said polymer forming said polymeric template; (ii) aggregated crystals of said alkaline earth metal salt; and/or (iii) aggregated crystals of said alkaline earth metal salt coated on the surface of said polymer; said strands being arranged such that primary pores having a mean width from about 5 to about 300 microns are defined between at least two of said strands; said construct further comprising secondary walls extending from surfaces of said strands, said secondary walls comprising crystals of said alkaline earth metal salt; said secondary walls being arranged such that said construct includes secondary pores having a mean width from about 0.01 to about 5 microns defined between at least two secondary walls.

104. The pharmaceutical excipient of claim 103, wherein said primary walls of said construct have a mean width about 50 to about 500 microns.

105. The pharmaceutical excipient of claim 104, wherein said secondary walls of said construct have a mean width from about 0.01 to about 5 microns.

106. A pharmaceutical excipient, comprising particles comprising a porous matrix of a polymer template and an alkaline earth metal salt in crystalline form defining a construct, said construct comprising strands defining primary walls having a mean width about 50 to about 500 microns, said primary walls comprised of (i) said polymer forming said polymeric template; (ii) aggregated crystals of said alkaline earth metal salt; and/or (iii) aggregated crystals of said alkaline earth metal salt coated on the surface of said polymer; said strands being arranged such that primary pores having a mean width from about 5 to about 300 microns are defined between at least two of said strands; said construct further comprising secondary walls extending from surfaces of said strands, said secondary walls having a mean width from about 0.01 to about 5 microns and comprising crystals of said alkaline earth metal salt; said secondary walls being arranged such that said construct includes

secondary pores having a mean width from about 0.01 to about 5 microns defined between at least two secondary walls.

107. The pharmaceutical excipient of claim 106, which has a specific surface area greater than $10m^2/g$.

108. The pharmaceutical excipient of any of claims 101 to 107, which has a specific surface area greater than $10m^2/g$ to about $100\ m^2/g$.

109. The pharmaceutical excipient of any of claims 101 to 107, wherein said polymer of said polymeric template comprises from about 5 to about 95% by weight of said pharmaceutical excipient, and the remaining portion of said pharmaceutical excipient comprises said alkaline earth metal salt.

110. The pharmaceutical excipient of any of claims 101 to 107, wherein said polymer of said polymeric template comprises from about 20 to about 80% by weight of said pharmaceutical excipient, and the remaining portion of said pharmaceutical excipient comprises said alkaline earth metal salt.

111. The pharmaceutical excipient of any of claims 101 to 110, wherein said alkaline earth metal salt is selected from the group consisting of calcium phosphate, calcium carbonate, calcium sulphate, calcium silicate, and mixtures thereof.

112. The pharmaceutical excipient of any of claims 101 to 110, wherein said alkaline earth metal salt is selected from the group consisting of calcium phosphate, calcium carbonate, and mixtures thereof.

113. The pharmaceutical excipient of any of claims 101 to 112,wherein said polymer comprising said polymeric template is selected from the group consisting of a pharmaceutically acceptable natural or synthetic polysaccharide.

114. The pharmaceutical excipient of claim 113, wherein said polymer is dextran.

115. The pharmaceutical excipient of claim 113, wherein said polymer is a polysaccharide gum.

116. The pharmaceutical excipient of claim 115, wherein said polysaccharide gum comprises xanthan gum.

117. The pharmaceutical excipient of claim 103 or 106, wherein the primary walls of the construct have a mean width from about 10 to about 200 microns.

118. The pharmaceutical excipient of claim 103 or 106, wherein the primary walls of the construct have a mean width from about 10 to about 50 microns.

119. The pharmaceutical excipient of claim 103 or 106, wherein the secondary walls of the construct have a mean width from about 0.5 to about 2 microns.

120. The pharmaceutical excipient of claim 103 or 106, wherein the primary pore size is from about 10 to about 50 microns.

121. The pharmaceutical excipient of claim 103 or 106, wherein the secondary pores in the construct have a mean size range from about 0.01 to about 2 microns.

122. A pharmaceutical product, comprising the pharmaceutical excipient of any of claims 101 - 120 onto which a therapeutic agent is coated.

123. The pharmaceutical product of claim 122, wherein said therapeutic agent has an aqueous solubility of not greater than about 1 in 30 to 1 in 100, weight/volume, when measured at a temperature in the range of 15 to 25°C.

124. The pharmaceutical product of claims 122 or 123, wherein said therapeutic agent is a chemical or biologic agent.

125. The pharmaceutical product of claims 122 or 123, wherein the pharmaceutical excipient is coated to a level from about 1 to about 50% w/w with said therapeutic agent.

126. The pharmaceutical product of claims 122 or 123, which has a mean particle size from about 10 to about 500 microns.

127. The pharmaceutical product of claims 122 or 123, which has a mean particle size from about 50 to about 300 microns.

128. The pharmaceutical product of claims 122 or 123, which has a mean particle size from about 100 to about 250 microns.

129. The pharmaceutical product of claim 122, wherein said therapeutic agent is coated onto said pharmaceutical excipient via a process selected from the group consisting of solvent evaporation, spray drying and freeze drying.

130. An oral solid dosage form comprising a unit dose of the pharmaceutical product of any of claims 122 to128.

131. The oral solid dosage form of claim 130, which is in a form selected from the group consisting of a pharmaceutical powder, a capsule, or a tablet.

132. The pharmaceutical excipient of claim 108, which has a specific surface area from about 5 to about 50 mg^2/g.

133. The pharmaceutical excipient of claim 108, which has a specific surface area from about 10 to about 40 m^2/g.

134. A method of preparing a pharmaceutical excipient, comprising

dissolving a pharmaceutically acceptable polymeric material into a phosphate or carbonate solution;

adding calcium chloride to the solution containing the dissolved polymeric material in a controlled manner; and thereafter

collecting the resultant solid material comprising a construct comprising calcium phosphate or carbonate crystals in intimate association with a polymer template, such that said construct has a specific surface area greater than about 10 m^2/g.

135. The method of claim 134, wherein said calcium chloride is added in a manner such that a porous matrix of a polymer template and said calcium phosphate or carbonate in crystalline form defining a construct is formed, said construct comprising strands defining primary walls having a mean width about 50 to about 500 microns, said primary walls comprised of (i) said polymer forming said polymeric template; (ii) aggregated crystals of said alkaline earth metal salt; and/or (iii) aggregated crystals of said alkaline earth metal salt coated on the surface of said polymer; said strands being arranged such that primary pores having a mean width from about 5 to about 300 microns are defined between at least two of said strands; said construct further comprising secondary walls extending from surfaces of said strands, said secondary walls having a mean width from about 0.01 to about 5 microns and comprising crystals of said alkaline earth metal salt; said secondary walls being arranged such that said construct includes secondary pores having a mean width from about 0.01 to about 5 microns defined between at least two secondary walls.

136. The method of claim 134 or 135, wherein the following materials are utilized: Na_2HPO_4: 2 $moIL^{-1}$, in the range of 0.1 to 10 $moIL^{-1}$. $CaCl_2$: 4 $moIL^{-1}$, in the range of 0.1 to 10 $moIL^{-1}$. Template Material: 25 t 85% w/w, in the range of 5 to 95% w/w, wherein % w/w is defined in relation to the weight of template material and the weight of calcium phosphate or carbonate.

137. The method of any of claims 134 to 136, further comprising removing the polymeric template from the construct substantially without reducing the specific surface area of the resultant pharmaceutical excipient.

138. The method of any of claims 134 to 137, further comprising breaking down the resultant pharmaceutical excipient into an end product pharmaceutical excipient having a mean particle size from about 10 to about 500 microns.

139. The method of any of claims 134 to 137, further comprising breaking down the resultant pharmaceutical excipient into an end product pharmaceutical excipient having a mean particle size from about 50 to about 300 microns.

140. The method of any of claims 134 to 137, further comprising breaking down the resultant pharmaceutical excipient into an end product pharmaceutical excipient having a mean particle size from about 100 to about 250 microns.

141. The method of any of claims 134 to 137, further comprising combining said pharmaceutical excipient with a therapeutic agent in a manner such that the therapeutic agent is coated onto the pharmaceutical excipient.

142. The method of claim 141, wherein said therapeutic agent is coating onto the surface of said pharmaceutical excipient via a method selected from the group consisting of solvent evaporation, freeze drying, and spray drying.

143. The method of claim 141 or 142, further comprising incorporating the pharmaceutical excipient coated with the therapeutic agent into an oral solid dosage form.

144. The method of claim 141 or 142, further comprising incorporating the pharmaceutical excipient coated with the therapeutic agent into an oral solid dosage form selected from the group consisting of a pharmaceutical powder, a capsule, and a tablet.

145. The method of claim 141 or 142, wherein said therapeutic agent is coating onto the pharmaceutical excipient at a level, e.g., from about 1% to about 50% w/w.

146. A method of treatment, comprising administering the oral dosage form of claim 130 or 131 to a human patient.